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| PRE-APPEAL BRIEF REQUEST FOR REVIEW | | Docket Number (Optional) 5490-000366 | |
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] On _____ Signature _____ Typed or printed name _____ | Application Number 10/702,335 | | Filed November 6, 2003 |
| | First Named Inventor James W. Scott et al | | |
| | Art Unit 3733 | | Examiner James L. Swiger, III |
| <p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number 38,043 / 44,626.</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> | | | |
|  _____ Signature | | Richard W. Warner / Maria Comninou _____ Typed or printed name | |
| | | 248-641-1600 _____ Telephone number | |
| | | November 19, 2007 _____ Date | |
| NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*. | | | |
| <input type="checkbox"/> *Total of _____ forms are submitted. | | | |

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/702,335
Filing Date: November 6, 2003
Applicants: James W. Scott et al.
Group Art Unit: 3733
Examiner: James L. Swiger, III
Title: TIBIAL PREPARATION APPARATUS AND METHOD
Attorney Docket: 5490-000366

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Alexandria, Virginia 22313-1450

REASONS/REMARKS/ARGUMENTS
WITH PRE-APPEAL BRIEF REQUEST FOR REVIEW

SUMMARY

Applicants submit that there is a clear error in the prima facie case of the rejections made in the Final Office Action mailed August 24, 2007. Specifically, the rejections included in the Office Action fail to account for at least one element required in each of the rejected claims.

STATUS OF THE CLAIMS

The claims stand as amended in the Amendment filed on June 4, 2007. An Amendment filed on October 12, 2007 in response to the Final Office Action mailed on August 24, 2007 was not entered. An Advisory Action was mailed on October 26, 2007.

In the Final Office Action mailed on August 24, 2007, claims 1-6, 8-12, 14-19, and 27-32 stand rejected. Claims 1-5, 27-28, and 31-32 stand rejected under 35 U.S.C. §102(b) as being anticipated by Johnson et al (U.S. Pat. No. 5,683,469). Claims 8-12, 14, 16, and 29-30 stand rejected under 35 U.S.C. §102(b) as being anticipated by Burkinshaw et al (U.S. Pat. No. 6,159,216). Claim 6 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson et al. Claim 15 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Burkinshaw et al. Claims 17-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Burkinshaw et al in view of Johnson et al.

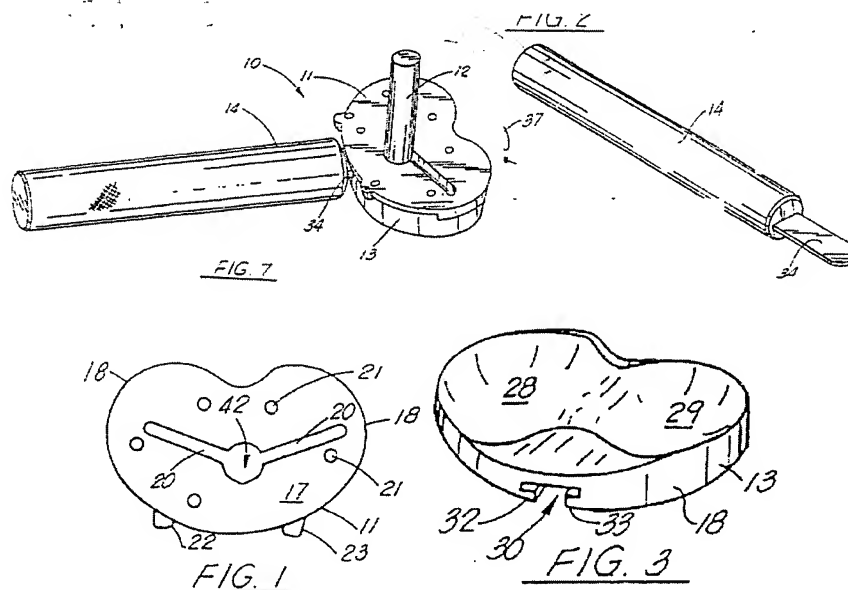
Of the rejected claims, claims 1, 8, 17, and 31 are independent claims. The rejections of all the dependent claims rely on Johnson et al or on Burkinshaw et al or on their combination to provide all the elements of the respective base claims.

REMARKS AND ARGUMENTS

Failure to establish prima facie case of rejection for independent claims 1 and 31 because at least one limitation is identified as not disclosed by Johnson et al .

Johnson et al appears to disclose a tibial trial prosthesis 10 having a trial plate/tray 11 with a central opening 42 receiving a stem/plug 12 perpendicular to the trial plate. See FIGS. 1-2 and 7, and column 5, lines 54-57 and 64. A lever (handle) 14 having a tab 34 is used to engage a slot 30 of an insert 13 for removing or attaching the insert 13 to the tray 11. See FIGS. 3, 5 and 7, and column 6, lines 37-40. The lever 34 is attached symmetrically and along the centerline of the insert 13 and is in no way attached at an offset, such as a lateral or medial offset, relative to the tray 11, as seen in FIGS. 2 and 7 below:

Johnson et al



In contrast, the claimed invention has a handle that is attached at an offset to the tibial tray, as seen in FIG. 1 below:

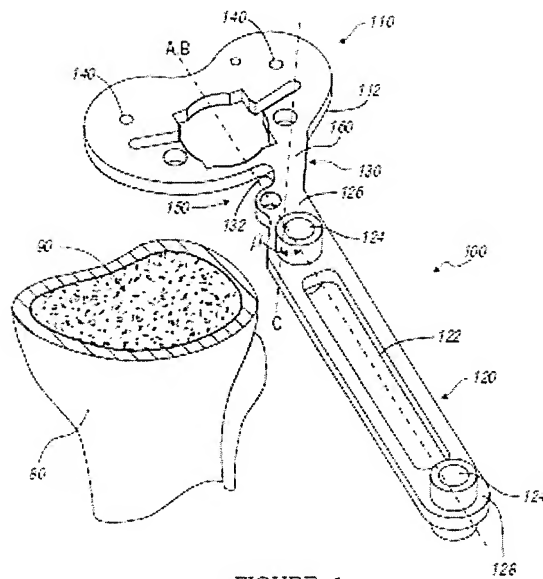


FIGURE 1

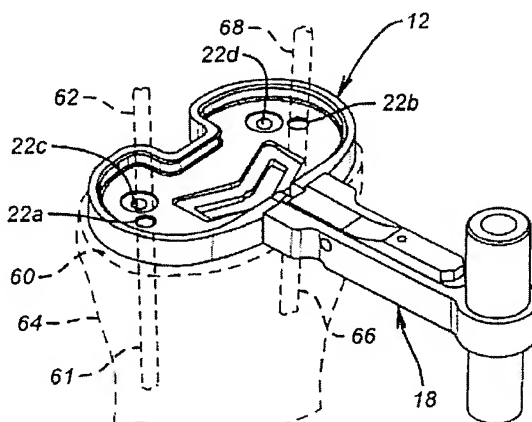
Regarding claim 1, Johnson et al fails to disclose a handle having a longitudinal axis coaxially aligned to the center axis of the base, **the handle coupled to the base only at an anterior base location that is offset relative to the center axis.** Johnson et al does not disclose any handle that can be considered to be attached at an offset point relative to the tibial base. The Examiner indicated in the interview of October 9, 2007 that the handle of Johnson et al is adjustable or may provide some “play”, such that the handle axis may become slightly offset. Applicants cannot find such disclosure in Johnson et al. The handle 14 of Johnson et al has a tab 34 that is slidably inserted into a slot 30 of the plastic insert, and the entire assembly of tray 11, insert 13, and stem 12 can be rotated by rotating lever 14. See column 6, lines 30-37. There is no disclosure that the handle/lever 14 can be rotated or adjusted relative to the tray 11 or the insert 13 to become attached at an offset. Claim 1 recites that the handle is coaxially aligned to the center axis of the tibial base, but is coupled to the base only at a location that is offset relative to the center axis of the tibial base.

Further, and regarding claim 4, which depends from claim 1, Johnson et al fails to disclose a link extending from the tibial base at an offset relative to the center axis and coupled to the handle. Regarding claim 6, which depends from claim 1, the tibial base of Johnson et al is clearly one-sided and not reversible because it includes a plastic insert 13 and a stem 12 that can be attached only on one side.

Similarly, and regarding independent claim 31, Johnson et al fails to disclose a handle attached at an anterior location of the tibial base that is **offset from the longitudinal axis of the handle**.

Failure to establish prima facie case of rejection for independent claims 8 because at least one limitation is identified as not disclosed by Burkinshaw et al .

Burkinshaw et al discloses a tibial baseplate trial member 12 and a removable handle 18. The handle is symmetric and is symmetrically attached to the baseplate, with no offset of any kind. See FIGS. 1 and 2.



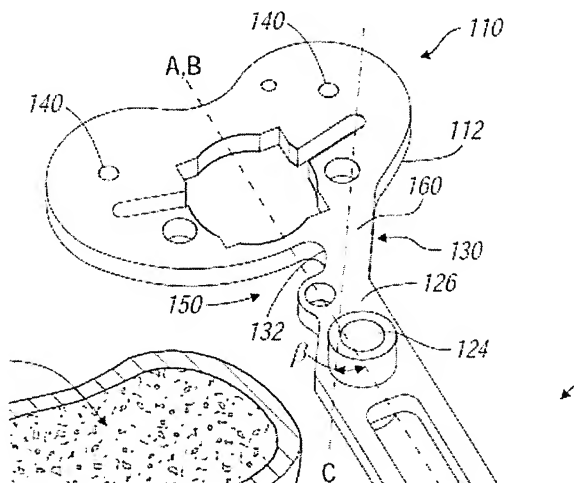
Regarding independent claim 8, Burkinshaw et al clearly fails to disclose a link having first and second ends, the first end coupled to the base only at a position that is medially offset from the center axis, and a handle having a central longitudinal axis coaxially aligned with the center axis of the base, the handle coupled to the second end of the link. Therefore, claim 8 is not anticipated by Burkinshaw et al and/or is not obvious in further view of Johnson et al.

Further, and regarding claim 16, which depends from claim 8, Burkinshaw et al fails to disclose that the link has a curved portion defining a lateral clearance extending beyond the center axis of the tibial base.

Failure to establish prima facie case of rejection for independent claims 17 because at least one limitation is identified as not disclosed by Johnson et al and Burkinshaw et al.

As discussed above, neither Burkinshaw et al nor Johnson et al disclose any handle that is attached at an offset to a tibial base or tray. Their combination still lacks the “offset” attachment element. Accordingly, and regarding claim 17, Johnson et al and Burkinshaw et al, either

individually or in combination fail to disclose a handle having a central longitudinal axis parallel to the center axis of the tibial base, the handle having a first end, the first end coupled to the base, **the first end having a medially offset cutout, the cutout defining a lateral clearance extending beyond the center axis of the base and beyond the longitudinal axis of the handle,** as clearly shown in FIG. 1 of the present application:



Applicants respectfully submit that were the Examiner's interpretation of the art to stand, it would render the ordinary meaning of the word "offset" an empty shell and would eliminate the "offset" limitation from the language of the claims.

Conclusion

Applicants respectfully submit that the standing rejections maintained by the Examiner in the Final Office Action mailed August 24, 2007 fail to establish the necessary prima facie case of rejection. Applicants respectfully request that the Panel review the rejections and direct the Examiner to withdraw each rejection as clearly erroneous.

Respectfully submitted

Date: November 19, 2007

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